K003963

FEB 2 8 2001

Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: George M. Plummer
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

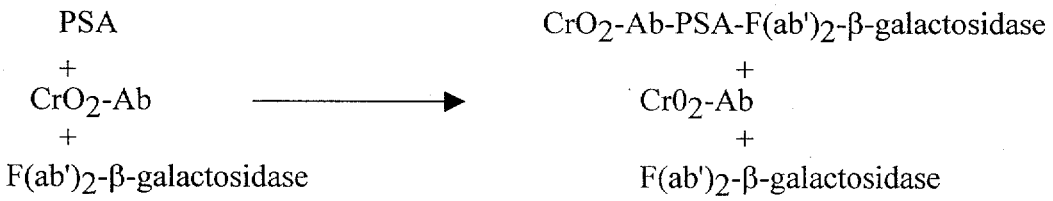
Date of Preparation: December 21, 2000

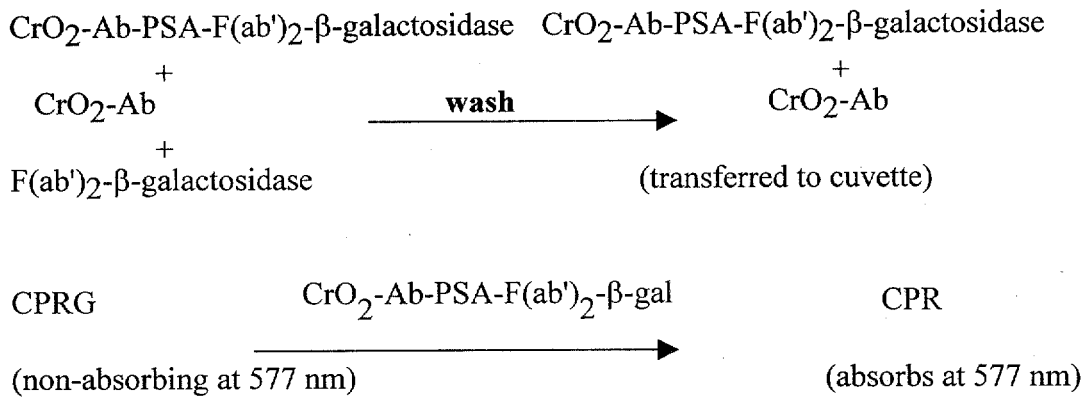
Name of Product: PSA Flex® Reagent Cartridge

FDA Classification Name: Prostate Specific Antigen for the management of prostate cancer

Predicate Device: Dade Behring PSA Flex® reagent cartridge (K973101)

Device Description: The Dimension® PSA Flex® reagent cartridge method is a solid phase, two-site, one-step immunoenzymetric assay designed for use on the Dimension® clinical chemistry system with the Heterogeneous Immunoassay Module. The Dimension® clinical chemistry system with the Heterogeneous Immunoassay Module system is a fully automated random access analyzer. Sample is incubated with chromium dioxide particles (CrO_2) coated with monoclonal antibodies specific for a binding site on the PSA molecule and conjugate reagent [β-galactosidase (β-gal) labeled monoclonal antibodies specific for a second binding site on the PSA molecule] to form a particle/PSA/conjugate sandwich. Unbound conjugate and analyte are removed by magnetic separation and washing. The sandwich bound β-gal catalyzes the hydrolysis of chlorophenol red-β-d galactopyranoside (CPRG) to chlorophenol red (CPR). The color change measured at 577 nm due to the formation of CPR is directly proportional to the concentration of PSA present in the patient sample.





Intended Use: The PSA method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic test intended to quantitatively measure prostate specific antigen (PSA) in human serum. Measurements of PSA are used as an aid in the management of prostate cancer.

Comparison to Predicate Device:

Item	Original PSA Flex®	Revised PSA Flex
Sample Type	Serum	Serum
Methodology	Immunoprecipitation	Immunoprecipitation
Detection	Bichromatic endpoint (340 and 700 nm) (turbidimetry)	Bichromatic endpoint (340 and 700 nm) (turbidimetry)
Reagents		
Well 1	PSA Conjugate	PSA Conjugate + Bovine gamma Globulin (BgG)
Well 3	Antibody-CrO_2	Antibody-CrO_2
Well 4,5,6	CPRG	CPRG
Well 7	Substrate Diluent	Substrate Diluent

Comments on Substantial Equivalence:
Split sample comparison between the revised PSA Flex® reagent cartridge and the current PSA Flex® reagent cartridge gave a correlation coefficient of 0.999, slope of 0.993, and an intercept of –0.21 mg/dL when tested with 199 clinical patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 8 2001

Mr. George M. Plummer
Quality Assurance and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Newark, Delaware 19714

Re: K003963
Trade Name: Dimension® PSA Flex® Reagent Cartridge
Regulatory Class: II
Product Code: LTJ
Dated: December 21, 2000
Received: December 22, 2000

Dear Mr. Plummer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

Device Name: PSA Flex® reagent cartridge

Indications for Use:
The PSA method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic test intended to quantitatively measure prostate specific antigen (PSA) in human serum. Measurements of PSA are used as an aid in the management of prostate cancer.

George M. Plummer
Quality Assurance and
Compliance Manager

December 19, 20000

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maheri

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003965

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CRF 801.109)

(Optional Format 1-2-96)